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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,422	02/27/2004	Boris Y. Shekunov	FER-14668.001	5255
7609	7590	10/24/2006		
RANKIN, HILL, PORTER & CLARK, LLP 925 EUCLID AVENUE, SUITE 700 CLEVELAND, OH 44115-1405			EXAMINER DRODGE, JOSEPH W	
			ART UNIT 1723	PAPER NUMBER
DATE MAILED: 10/24/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/789,422	Applicant(s) SHEKUNOV ET AL.	
	Examiner Joseph W. Drodge	Art Unit 1723	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

The Double Patenting Rejection has been mitigated by the Terminal Disclaimer filed 9/12/2006 which has been approved.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-16 remain rejected under 35 U.S.C. 102(b) as being anticipated by Sievers et al patent 5,639,441. Sievers et al disclose producing of particles [as in claims 10 and 15] comprising providing supercritical fluid, 1<sup>st</sup> solvent soluble in such fluid, 2<sup>nd</sup> insoluble solvent, the 2<sup>nd</sup> solvent optionally being partially soluble in the 1<sup>st</sup> solvent, and solute, contacting these together to form a solution, then contacting the solution with supercritical fluid to extract 1<sup>st</sup> solvent from the solution and precipitate the solute in the form of particles suspended in the 2<sup>nd</sup> solvent (all disclosed at column 5, line 66-column 6, line 61, column 6, line 66-column 7, line 5 indicate that the solution of solvents and solute are formed before contacting with supercritical fluid).

The solute contains a biologically active substance as in claims 2 and 11 (column 5, lines 22-36). The supercritical fluid is carbon dioxide as in claim 3 (column 6, line 44). There may be plural solutes as in claim 4 (column 5, lines 36-40). There is also a 2<sup>nd</sup> solute comprising a polymer, wax or lip as in claims 5 and 12 (column 5, line 37). The 1<sup>st</sup> solvent may an alcohol or acetone organic solvent as in claims 6, 13 and 7

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(column 5, lines 66-67 and column 6, line 51) while the 2<sup>nd</sup> solvent is water (column 6, lines 57-59) as in claim 8. The particle size is from 10 nm to 10 microns (column 6, lines 33-36) for claims 9 and 14.

Both of the fluids/solvents may be or include different supercritical fluids or liquids (column 6, lines 49-52). This portion of text in combination with text of column 7, lines 15-20 gives the option of one of the supercritical fluids/liquids entering the gaseous phase and such fluid/liquid and/or co-solvent thereof (column 6, lines 53-56) precipitating a gas-borne dispersion or suspension of particles while the other supercritical fluid or liquid remains, at least initially in supercritical state. Such dispersion may, in a preferred embodiment comprise particles of solid or liquid and may comprise the dissolved substance in solution or suspension, optionally in an organic solvent such as methanol (column 6, lines 17-24 supported by column 5, line 66-column 6, line 4 and column 6, lines 49-56).

For claim 16, Sievers also disclose apparatus features of extraction vessel 20, means for removing formed particles 22,34,24, 1<sup>st</sup> supercritical fluid reservoir source 10, 1<sup>st</sup> pump 12, 2<sup>nd</sup> solution reservoir source 14, 2<sup>nd</sup> pump 16, and a restrictor, backpressure maintaining means for removing the mixture at column 11, line 66-column 12, line 5. Sievers infers that flow control restrictors are interchangeable, or combinable, with flow control release valves, as instantly claimed, at column 10, lines 55-56.

Applicant's arguments filed on October 18, 2006 have been fully considered but they are not persuasive. It is argued that Sievers forms a gas-borne dispersion of particles, not a suspension of particles in a solvent. It is submitted that the foregoing discussion of Sievers disclose embodiments or options where a gas-borne dispersion of particles is formed, with the particles comprising dissolved substance in solution or suspension.

It is argued that Sievers does not disclose separation of a first solvent from the suspension of particles while the supercritical fluid is in a supercritical state. It is submitted that column 6, lines 17-20 and column 7, lines 15-20 indicate that one supercritical fluid may pass into a gaseous state while the other supercritical fluid remains in a supercritical state.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Drodge at telephone number 571-272-1140. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached at 571-272-1151. The fax phone number for the examining group where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either private PAIR or Public PAIR, and through Private PAIR only for unpublished applications. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JWD

October 18, 2006

  
JOSEPH DRODGE  
PRIMARY EXAMINER